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Predictors of Functional Outcomes Following Limb Salvage Surgery for Lower-Extremity Soft Tissue Sarcoma

A.M. DAVIS, BScPT, MSc, PhD,[1]* S. SENNIK,[1] A.M. GRIFFIN, BSc,[1] J.S. WUNDER, MD, FRCSC,[1] B. O'SULLIVAN, FRCPC,[2] C.N. CATTON, FRCPC ,[2] AND R.S. BELL, MD, FRCSC[1]

[1]*University Musculoskeletal Oncology Unit, Mount Sinai Hospital and the University of Toronto, Toronto, Canada*

[2]*Department of Radiation Oncology, Princess Margaret Hospital, University Health Network and the University of Toronto, Toronto, Canada*

Background and Objectives: Patient function has been conceptualized by clinical measures such as joint motion, muscle strength, disability, and general health status. The purpose of the current study was to evaluate tumor and treatment variables predictive of these conceptually different posttreatment functional outcomes in patients treated with limb preservation surgery for lower-extremity soft tissue sarcoma.

Methods: One hundred seventy-two patients with minimum 1-year follow-up were evaluated using the following outcomes: impairment, measured by the 1987 and 1993 versions of the Musculoskeletal Tumor Society Rating Scale (MSTS); disability, measured by the Toronto Extremity Salvage Score (TESS); and general health status, using the Short Form-36 (SF-36). Tumor and treatment-related variables (age, gender, presenting disease status, anatomic site, tumor size, grade, depth, prior excision, irradiation, bone resection, motor nerve sacrifice, and complications) were extracted from the STS database.

Results: Large tumor size, bone resection, motor nerve resection, and complications were predictive of lower MSTS 1987 and 1993 scores. Patients with large, high-grade tumors who required motor nerve resection were more disabled, as reflected by lower TESS scores. Only age and prior surgery were adverse predictors of SF-36 score.

Conclusions: These results demonstrate that different factors are predictive of different patient outcomes, specifically, impairment, disability, and general health status. It is important to define function when counseling patients regarding their potential recovery based on tumor and treatment-related variables.

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KEY WORDS: **soft tissue sarcoma; limb preservation; function; predictive factors; outcome**

INTRODUCTION

The "function" of patients treated by limb-preservation surgery for extremity sarcoma has been documented using a variety of outcome measures. These outcome measures conceptualize function differently and include clinical measures such as range of motion and muscle strength [1,2]; measures of activities of daily living (ADL), such as those of Lampert et al. [1] and Convery et al. [3]; scales, such as that of Scranton et al. [4] which combine both clinical measures and ADL [2]; the Musculoskeletal Tumor Society Rating Scale (MSTS) 1987 [5], which includes symptoms and clinical measures [6]; the revised MSTS [7], which includes symptoms, mobility, and use of assistive devices; and generic health status measures [8], such as the Sickness Impact Profile [9,10].

*Correspondence to: Aileen M. Davis, BScPT, MSc, PhD, Suite 476, Mount Sinai Hospital, 600 University Avenue, Toronto, Canada M5G 1X5. Fax No.: (416) 586-8397. E-mail: davis@mshri.on.ca

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Consequently, in regard to counseling patients about their potential functional outcome following treatment, the literature does not provide clear direction. Furthermore, predictors of functional outcome may vary depending on what aspect of function is being measured.

The purpose of the current study was to evaluate the tumor and treatment variables predictive of functional outcome in a series of patients treated by limb-preservation surgery for soft tissue sarcoma (STS) of the lower extremity. Function was conceptualized according to the World Health Organization (WHO) International Classification of Impairments, Disabilities, and Handicaps (ICIDH) [11]. Impairments are "any loss or abnormality of psychological, physiological, or anatomical structure or function" [11]. Disability is "any restriction or lack of ability to perform an activity in the manner or within the range considered normal for a human being" [11]. The measures used to evaluate function were the MSTS [5], the revised MSTS [7], the Toronto Extremity Salvage Score (TESS) [12], and the Short Form-36 (SF-36) [13]. The symptoms and content of the 2 MSTS scales most closely follow the definition of impairment [11]. TESS [12], a measure of physical disability developed for the extremity sarcoma population, was developed based on the WHO definition of disability [11]. SF-36 is a generic health status measure that Ware [13] intended to encompass the WHO definition of health [14], i.e., a state of complete physical, mental, and social well-being and not merely absence of disease. The SF-36 includes impairments and disabilities. Based on these varying conceptualizations of function, we anticipated that different factors might be predictive of the various measures of function.

MATERIALS AND METHODS

Subjects were eligible for this study if they underwent limb-preservation surgery for STS of the lower extremity (i.e., distal to the posterior iliac crest and inguinal line), spoke and/or read English, consented to evaluation, and had a minimum of 1 year of follow-up for function. If a patient developed a local or systemic recurrence, the last evaluation prior to recurrence was used. One year was chosen as the minimum follow-up because data from our group have shown that function scores plateau after 6 months for STS patients [6,15]. The mean time from surgery to functional assessment was 45 months (SD = 23.1).

The sample included 172 STS cases treated during the period January 1986 to December 1995. TESS was developed in 1994, so potentially eligible patients (n = 54) who developed or died of metastases prior to this time were not included as their function had not been assessed with TESS. Ten eligible patients were lost to follow-up, a further 27 had missing data on 1 or more questionnaires, and 1 patient was cognitively challenged and unable to complete the evaluation. During this period, 17 patients were treated by primary amputation, and due to the small number of these cases, the study was limited to patients treated by limb preservation.

All STS cases were assessed by the multidisciplinary team, staged, and treated according to the protocol previously published by our group [16].

The clinician completed the MSTS [5] and the revised MSTS [7], and the patient completed the TESS [12] and the SF-36 evaluations [13]. The MSTS [5] consists of 7 items: pain, range of motion, strength, joint stability, joint deformity, emotional acceptance, and overall function. Each item is rated on a scale from 0 to 5, with a maximum score of 35. The revised MSTS [7] has 6 items (pain, overall function, emotional acceptance, walking ability, gait aid, and gait handicap or limp), each rated from 0 to 5. The score, out of 30, is converted to a percentage. The TESS [12] is a 30-item questionnaire in which the patient indicates the level of difficulty experienced in performing everyday activities such as dressing, grooming, mobility, work, sports, and leisure. Each item is rated on a scale ranging from 1 to 5, with the total score calculated as a percentage. The TESS has demonstrated reliability, validity, and responsiveness for the extremity tumor population [12,15]. The SF-36 [13] has 36 items that are combined into 8 subscale scores: physical function, role-physical, bodily pain, general health, vitality, social function, role-emotional, and mental health. The maximum score for each subscale is 100. A physical component score (PCS) and a mental component score (MCS) can also be created from these 8 subscales [17]. For each measure, higher scores indicate a higher level of function.

Tumor and treatment-related variables were prospectively collected and stored in a password-protected database. The variables extracted from the database for this study were age; gender; presenting disease status (e.g., primary, locally recurrent); site coded as pelvis/hip, distal thigh/knee/proximal leg, and distal leg/foot and ankle; size based on maximum tumor diameter in centimeters; low vs. high grade; superficial vs. deep to fascia; prior incomplete excision (no/yes); irradiation (no/yes); bone resection (no/yes); motor nerve resection (no/yes); and complications (no/yes). Nerve resection was defined by resection of a major motor nerve: sciatic, femoral, obturator, posterior tibial, or peroneal. Complications included major wound dehiscence or infection (requiring return to the operating room) or fracture. The preoperative MSTS [5] score was available for all patients, and we initially intended to use this to control for preoperative function. However, due to lack of variability in the data, this score was not included in the analysis.

Descriptive statistics, including frequencies, means, and standard deviations, were calculated for all patient

and treatment descriptors and for the outcome measures as appropriate to the data type. To support that the MSTS [5], revised MSTS [7], TESS [12], and SF-36 [13] evaluated different constructs of function, correlation coefficients were calculated. The constructs of function evaluated by the MSTS [5], revised MSTS [7], TESS [12], and physical function and PCS of the SF-36 [17] were hypothesized to have moderate to high correlations, ranging from 0.4 to 0.8. The relationship with the MCS was anticipated to be lower, ranging from 0.3 to 0.5.

All patient- and treatment-related variables were evaluated as independent predictors of each of the functional outcomes in univariate analysis using linear regression. Variables that were significant at the 0.05 level were then evaluated in a multivariate model using stepwise regression. All analyses were conducted using the Statistical Package for the Social Sciences, version 8.0 (SPSS, Chicago, IL).

RESULTS

The mean age of the 172 patients was 51 years (SD = 15.2), with equal numbers of males and females. Eight patients had locally recurrent disease at the time of referral. Tumors were large (mean maximum diameter 8.3 cm), deep (134/172), and high-grade (127/172). Eighty-one percent of subjects (139/172) were treated with adjuvant radiotherapy. With mean follow-up of 45 months, 121 (70.2%) of the 172 are currently disease-free. Six patients developed a local recurrence at a mean of 44 months (SD = 23.1), and 45 relapsed systemically at a mean of 18.6 months (SD = 6.1). Table I provides complete details of the patients.

Table II details the scores on each of the outcome measures. For all measures, scores indicate a relatively high level of functioning for the average patient. The correlation matrix showing the relationship among the outcome measures is shown in Table III. Correlation coefficients between measures are in the range of 0.5 to 0.8, suggesting that one measure explains 25% to 64% of the comparative measure. The correlation coefficient of the 2 versions of the MSTS is higher at 0.9. This is expected as the 2 measures have 3 identical items (pain, emotional acceptance, and overall function). As anticipated, the MCS and the PCS of the SF-36 had a low correlation coefficient, not statistically different from 0.

Linear regression indicated that large tumor size, deep lesions, high grade, prior incomplete excision, bone resection, motor nerve sacrifice, and complications were univariate predictors of MSTS score [5]. Only large tumor size, bone resection, motor nerve resection, and complications remained adverse predictors in the multivariate model ($R^2 = 0.30$). The univariate predictors of the 1993 MSTS were very similar to those of the 1987 MSTS, with the addition of radiotherapy as a significant predictor. In multivariate analysis, large tumor size, high grade, bone resection, motor nerve sacrifice, and complications were significant predictors of MSTS score [7] ($R^2 = 0.27$).

Increased disability, as measured by TESS, was predicted by large tumor size, deep lesions, high grade, use of radiotherapy, bone resection, and motor nerve sacrifice in univariate modeling. However, only large tumor size, high grade, and neural sacrifice remained as multivariate predictors ($R^2 = 0.20$).

Health status is represented by the average of the 8 subscale scores of the SF-36 as this structure provides the best mathematical representation of the 36 items in this

TABLE I. Sample Descriptors for Patients Treated with Limb Salvage Surgery for Soft Tissue Sarcoma of the Lower Extremity (n = 172)

Descriptor	No.[a]
Age (years, mean ± SD)	51 ± 15.2
Gender	
Male	88
Female	84
Presenting status	
Primary	164
Local recurrence	8
Prior Excision	
No	91
Yes	81
Tumor histology	
Malignant fibrous histiocytoma	45
Liposarcoma	63
Other	64
Maximum tumor diameter (cm, mean ± SD)	8.3 ± 5.4
Grade	
Low	45
High	127
Depth	
Superficial	38
Deep	134
Site	
Pelvis/hip/proximal thigh	65
Distal thigh/knee/proximal leg	84
Distal leg/foot/ankle	23
Radiotherapy	
No	33
Yes	139
Bone resection	
No	154
Yes	18
Motor nerve resection	
No	151
Yes	21
Complications	
None	114
Wound	48
Fracture	7
Other	3
Disease status	
Continuously disease-free	121
Local recurrence	6
Systemic relapse	45

[a]Unless otherwise specified.

TABLE II. Functional Outcome Scores for Patients Treated for Soft Tissue Sarcoma of the Lower Extremity (n = 172)

Outcome	Mean	Standard deviation	Range
Musculoskeletal Tumor Society Rating Scale [5][a]	30.0	6.2	9–35
Musculoskeletal Tumor Society Rating Scale [7]	84.9	20.4	13–100
Toronto Extremity Salvage Score [12]	82.7	18.7	23–100
Short Form-36 [13, 17]			
Physical function	64.0	28.0	5–95
Role, physical	66.3	44.4	0–100
Bodily pain	74.0	26.8	0–100
General health	69.5	22.7	5–95
Vitality	61.1	21.6	0–100
Social function	82.9	25.6	0–100
Role, emotional	75.9	40.2	0–100
Mental health	75.4	20.1	4–96
Average of 8 subscales	71.1	22.9	8.2–100
Physical component score	44.4	11.9	17.1–64.1
Mental component score	52.1	11.1	13.8–72.9

[a]Maximum score is 35, whereas maximum score is 100 for all other measures. For all measures, higher scores indicate higher functional levels.

sample. As with a prior data set of lower-extremity tumor patients [15], the 8 subscale structure of SF-36 could not be reproduced because the items correlated with multiple subscales (data not shown). Increasing age, large tumor size, high grade, and prior incomplete excision of the tumor predicted a lower average SF-36 score in univariate analysis, whereas only age and prior incomplete excision maintained their significance in the multivariate model ($R^2 = 0.14$). Using the PCS of SF-36 based on item weights derived from the US population, only age and tumor size were significant predictors in multivariate modeling ($R^2 = 0.16$). None of the predictors was significantly related to MCS. The results of the univariate and multivariate models are summarized in Table IV.

Impairment or dysfunction at the organ level (e.g., the joint, muscle), as measured by the MSTS [5,7], increased when patients had large tumors, required bone resection and/or motor nerve resection to remove the tumor, and had treatment complications. Patients with large, high-grade tumors who required major motor nerve resection had greater physical disability or difficulty with routine daily activities as measured by the TESS [12]. General health status as measured by the SF-36 [13,17] was worse in older patients who had prior excision of tumor before referral to a specialized multidisciplinary treatment team.

DISCUSSION

This study has confirmed that, although outcome measures may purport to evaluate function, the underlying construct and definition of function vary such that different outcomes are achieved by patients depending on the measure. Further, the predictors of these conceptually different definitions of functional outcome vary. This has important implications for clinicians in counseling patients on their expected outcome following treatment for STS of the lower extremity.

The results of this study, using the MSTS [5], revised MSTS [7], TESS [12], and SF-36 [13] as measures of function, indicate that patients treated with limb preservation for lower-extremity STS have relatively high levels of functioning. These results are supported by those of others [1,2,6,18,19]. Lampert et al. [1], in a subgroup of 20 patients with lower-extremity STS, found that 4 patients reported severe functional limitations on a scale in which half the points are awarded for mobility. Stinson et al. [19] found that only 7% of 145 extremity STS patients experienced pain requiring narcotics. Thirty-two percent had moderate to severe limitations in range of motion, and 20% had moderate to severe decreases in manual muscle strength. Seven percent required an ambulatory aid. Bell et al. [6] reported that 68 (77%) of 88 patients with upper- and lower-extremity patients with

TABLE III. Spearman Correlation Coefficients of Functional Measures for Patients Treated With Limb-Salvage Sugery for Soft Tissue Sarcoma of the Lower Extremity

	MSTS 1987	MSTS 1993	TESS	SF-36 average[a]	SF-36 PF	SF-36 PCS	SF-36 MCS
MSTS 1987	1.00						
MSTS 1993	0.91	1.00					
TESS	0.71	0.76	1.00				
SF-36 average[a]	0.54	0.57	0.74	1.00			
SF-36 PF	0.63	0.65	0.78	0.75	1.00		
SF-36 PCS	0.60	0.61	0.80	0.81	0.89	1.00	
SF-36 MCS	0.00	0.10[b]	0.20	0.71	0.18[b]	0.16b	1.00

MSTS 1987, Musculoskeletal Tumor Society Rating Scale [5]; MSTS 1993, Musculoskeletal Tumor Society Rating Scale [7]; TESS, Toronto Extremity Salvage Score [12]; SF-36, Short Form-36 [13, 17]; PCS, physical component score; MCS, mental component score.

[a]SF-36, score based on average of the 8 subscale scores.

[b]Correlation coefficient is not statistically different from 0.

TABLE IV. Variables and *P* Values Predictive of Each of the Functional Scores in Univariate and Multivariate Analysis in Patients Treated with Limb-Salvage Surgery for Soft Tissue Sarcoma

Variable	MSTS 1987		MSTS 1993		TESS		SF-36 (average of 8 subscales)		SF-36 PCS		SF-36 MCS	
	Univariate	Multivariate	Univariate	Multivariate	Univariate	Multivariate	Univariate	Multivariate	Univariate	Multivariate	Univariate	Multivariate
Age	NS		NS		NS		0.003	0.001	0.001	0.002	NS	
Gender	NS		NS		NS		NS		NS		NS	
Large tumor size	0.000	0.000	0.000	0.000	0.000	0.000	0.001	NS	0.001	0.001	NS	
Site	NS		NS		NS		NS		NS		NS	
Depth	0.001	NS	0.004	NS	0.008	NS	0.025	NS	0.011	NS	NS	
Grade	0.003	NS	0.001	0.045	0.001	0.004	NS		NS		NS	
Prior incomplete excision	0.000	NS	0.001	NS	0.000	NS	0.005	0.007	0.024	NS	NS	
Use of radiotherapy	NS	NS	0.044	NS	0.002	NS	NS		NS		NS	
Bone resection	0.000	0.002	0.000	0.005	0.055	NS	NS		NS		NS	
Motor nerve sacrifice	0.001	0.006	0.005	0.039	0.001	0.007	NS		NS		NS	
Complications	0.000	0.003	0.000	0.012	NS	NS	NS		NS		NS	
R^2 of model	0.30		0.27		0.20		0.14		0.16			

MSTS 1987, Musculoskeletal Tumor Society Rating Scale [5]; MSTS 1993, Musculoskeletal Tumor Society Rating Scale [7]; TESS, Toronto Extremity Salvage Score [12]; SF-36, Short Form-36 [13,17]; PCS, physical component score; MCS, mental component score; NS, nonsignificant at $P = 0.05$.

STS scored better than the group mean (21/35 points) on the MSTS [5]. Robinson et al. [2] found that 37 (68%) of 54 patients reported excellent function despite loss of motion and muscle strength. Keus et al. [18] described a normal functioning limb in 69% of 104 patients, with 23% having mild loss of motion. Bell et al. [6] and Stinson et al. [19] included both upper- and lower-extremity STS patients in their samples, whereas Robinson et al. [2] and Keus et al. [18] included only patients with lower-extremity tumors.

In the current study, large tumor size, bone resection, motor nerve sacrifice (e.g., femoral, obturator, sciatic, peroneal, and posterior tibial nerves), and complications were predictive of a lower MSTS score [5], a measure of impairment. Large tumor size, high grade, bone resection, and motor nerve sacrifice were significant predictors of revised MSTS score [7], which combines both impairment and disability concepts. For TESS [12], a measure of physical disability, only large tumor size, high grade, and motor nerve sacrifice were significant predictors of lower scores in the multivariate analysis. For both revised MSTS [7] and TESS [12] scores, use of radiotherapy was a significant univariate predictor but failed to reach significance in the multivariate model. The fact that the use of radiotherapy was not predictive of lower MSTS [7] and TESS [12] scores when evaluated with other variables is likely due to the fact that all large, high-grade tumors in this series received radiotherapy. Health status scores, as measured by the SF-36 [13,17], are difficult to interpret as the items correlate with multiple subscales such that the 8-subscale structure is not upheld in the extremity tumor sample [15]. However, using a variety of scoring algorithms (physical function subscale alone, average of 8 subscales, or PCS), increasing age is the only consistent predictor of the SF-36 score, suggesting that the measure is unrelated to characteristics of the tumor or its treatment.

The differences in the variables predictive of functional outcome might be explained by the differing concepts of function evaluated by the measures. Disability, as measured in TESS [12], evaluates task performance such that compensatory actions may still permit completion of the task. Impairment measures, such as range of motion or manual strength included in the MSTS [5], are not amenable to these compensatory actions. Resection of a functioning muscle or a motor nerve results in loss of active joint motion and strength through the plane of movement. Extensive undermining of the muscle attachment in large tumors, excision of bone, and wound complications may increase soft tissue fibrosis such that the contractile and lengthening properties of the soft tissues are compromised. This may again limit range of motion and muscle strength. The compensatory back-knee gait observed following excision of the quadriceps compartment exemplifies this compensation. There is no active

extension of the knee joint, yet an individual is generally able to obtain stable stance in the gait cycle, rarely requiring the use of a brace or cane for ambulation.

The conceptual basis of the outcome measures used in this study differ not only in their underlying definition of function but also in how their content was derived. The 2 MSTS scales [5,7] were developed on the basis of clinicians' perceptions of important content, and the scores are based on a clinician's ratings. The TESS was developed on the basis of patient and clinician interviews with a subsequent patient survey to determine the content [12]. It is patient-completed and represents what is important to extremity sarcoma patients in measuring their physical disability. The SF-36 was developed for use in populations irrespective of disease [13,17].

Our group previously reported that large tumor size, complications, and motor nerve sacrifice were independent predictors of function as measured by the MSTS [5] in 88 upper- and lower-extremity STS patients treated with limb salvage [6]. Only tumor size and neural sacrifice remained significant in the multivariate model [6]. Tumor grade as a predictor of function was not evaluated in that study. Despite the inclusion of only lower-extremity STS patients in the current study, the multivariate model predicting MSTS score [5] is remarkably similar to that previous work (16 patients with updated functional data in the current study were included in the previous study). The strength of any predictive model lies in validating the results in a subsequent sample. The similarity between the results of Bell et al. [6] and the current work supports to the validation of the model.

This study reports outcome based on impairment, disability, and a generic health status measure. Work by Bessette et al. [20], Bombardier et al. [21], Hawker et al. [22], and Vickrey et al. [23] supports using multiple outcome measures. McCarthy et al. [24] recently published a study comparing impairment ratings, functional task performance, and patient's reported activity limitations using a generic measure, the Sickness Impact Profile [9,10]. Similar to this study, the correlations of the impairment ratings to the functional tasks and patient-reported function were moderate, with correlation coefficients of 0.57 and 0.55, respectively. The current results, as well as those cited above, reinforce the importance of understanding the underlying concept and definition in measures evaluating function.

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